DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 16 1998

The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Dingell:

This is in partial response to your letter of December 3, 1997 in which you submitted fifteen questions regarding imported foods. Enclosed please find our responses to questions 1(a), 1(b), 1(c), 11, 12(a), 12(c), 13, 14, and 15. The responses to the remaining questions will be forthcoming.

We appreciate your longstanding commitment to food safety and look forward to working with you and your staff on these issues.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure

cc: The Honorable Thomas J. Bliley, Jr.
Chairman, Committee on Commerce

RESPONSES FROM THE FOOD AND DRUG ADMINISTRATION TO QUESTIONS FROM THE HONORABLE JOHN D. DINGELL, RANKING MEMBER, COMMITTEE ON COMMERCE

1(a) Does the FDA have methods and procedures for detecting the various types of microbial, viral, and parasitic contamination of fresh fruits and vegetables that are imported into the United States? Please describe those methods and procedures.

We have some methods and procedures and are working to develop additional ones. The critical need for rapid, accurate methods to detect, identify, and quantify pathogens in a wide variety of environments (e.g. field, manufacturing plant, trucks, other forms of transportation) prompted the Food and Drug Administration (FDA or the Agency) to allocate a significant portion of the Fiscal Year (FY) 98 Food Safety Initiative (FSI) funds to the development of microbial, viral, and parasitic detection methods.

FDA has validated methods for detecting bacterial pathogens in a wide variety of foods; however, methods for detecting parasites and viruses are not as extensive and their use on fruits and vegetables is very limited. FDA methods for the detection of these contaminants are described in the FDA Bacteriological Analytical Manual (8th Ed.). A revised edition of this manual will be published in the first quarter of 1998. (We would be happy to provide the Committee with a copy of this edition once it is available.) Among the methods described are those for bacterial pathogens including Salmonella species and Listeria monocytogenes, parasitic pathogens Cyclospora cayetanensis and Cryptosporidium parvum, and viral hepatitis A. The ability to detect these organisms is very food matrix specific; methodology developed for one food matrix may not work effectively for another. For example, FDA has a method for hepatitis A for shellfish which must be revised to be effective for strawberries. The method currently used for Cyclospora on raspberries is inefficient due to the unique characteristics of the raspberry matrix.

Until recently, most microbiological, viral, and parasitic methods development has focused on seafood, processed foods, and occasionally on certain fresh produce as follow-up to a specific outbreak or incident. The methods for detecting the wide range of bacterial, viral, and parasitic pathogens in or on fresh fruits and vegetables are limited and are the focus of

one portion of our current methods development research. Existing pathogen methods developed for other commodities have not been validated for fresh produce, and, therefore, we do not know whether these methods are effective.

The FDA and the U.S. Department of Agriculture (USDA) are developing an interagency long-range research plan which includes the development of rapid methods for use with fresh produce.

1(b) How much is the FDA spending in the current fiscal year, and how much has been spent in each of the last four years to develop and/or improve the technology and testing capability needed to detect microbial, viral, and parasitic contamination of fresh fruits and vegetables?

Presented below are estimates of resources expended from FY 94 thru FY 97:

Year	Total Dollars*
FY 94	$1.360 million
FY 95	$1.440
FY 96	$1.520
FY 97	$1.580

*Note: These estimates include the administrative, computer, technical and other support required for research activities.

In FY 98, the Agency will continue the FY 97 base level resource commitment to develop and/or improve technology and testing for microbial, viral, and parasitic contamination on fresh produce ($1.58 million). In addition, a significant amount of the $7.85 million increase appropriated in FY 98 for FDA's foods research and risk assessment activities under the President's FSI will be devoted to work on fresh produce.

1(c) What does FDA expect to spend in each of the next three fiscal years to develop and/or improve the technology and testing capability needed to detect

microbial, viral, and parasitic contamination of fresh fruits and vegetables?

As noted in the response to question 1(b), in addition to the $1.58 million base level funding for research and risk assessment work in FY 98, the Agency expects to apply a significant amount of the $7.85 million appropriated for food safety activities associated with microbial, viral, and parasitic contamination of fresh produce. The Clinton Administration budget for FY 99 will be presented to Congress in coming weeks. The budget request for FY 2000 and 2001 will be dependent on the results of current efforts and budget funding decisions. FDA's priorities include: (1) the development of analytical methods for those pathogens that are known to have caused illness and (2) the optimization of these methods (e.g., automation) to assure that they can be applied efficiently and effectively.

In a research plan being developed with the USDA's Agricultural Research Service (ARS) for the Fresh Produce Initiative, several areas have been identified where food safety research needs to be expanded. These include efforts to: develop more rapid and accurate detection techniques; improve traditional food preservation techniques; develop more effective intervention strategies; and evaluate factors influencing antimicrobial resistance. The results of these research efforts will significantly improve FDA's and USDA's ability to conduct long-term surveillance and monitoring of both domestic and imported produce for safety hazards, increase the effectiveness of control and prevention strategies required to augment Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) guidance, and provide better guidance to deal with specific environmental factors, e.g., water quality, manure management, and worker hygiene.

11. Since NAFTA took effect, has the number of FDA inspections and the overall quality of FDA's inspection of Mexican produce imported into the United States improved, remained the same, or declined [please give a detailed explanation and justification for your answer].

Since December 1992, the year NAFTA took effect, the number of FDA inspections of Mexican produce offered for import into the U.S has been reduced. This reduction was based on the generally low violation rates observed for these products and on FDA's need to redirect inspection resources to other higher priority areas. Since 1993, the violation rate for Mexican produce has declined from 4.7% to 3.0% in 1996.

FDA has not yet completed its review and evaluation of the FY 97 data for FDA's inspection of Mexican produce. A

preliminary review of the data shows that FDA collected 2,056 samples and found 47 with illegal pesticide residues. This is approximately a 2.2% violation rate.

We believe the reduction in detentions is due to our preventive efforts. FDA, in concert with other U.S. agencies, works with the Mexican government to reduce the likelihood that illegal pesticides are used and that residues from legal pesticides do not exceed established tolerances.

FDA considers its relations and communications with Mexico to be excellent. FDA works with the Mexican Government and agricultural and pesticide industries to exchange information on FDA's regulatory system, the results of FDA's monitoring, and how to comply with U.S. pesticide tolerances. FDA and Mexico's Ministry of Health conduct an annual meeting and jointly have adopted a work plan for technical cooperation. FDA communicates with Mexican officials on a daily basis to address issues of concern. In addition, FDA has routine "Border Conferences" with government officials to discuss matters of mutual interest.

12. The 1993 GAO testimony stated that "because of inefficiencies and resource limitations, FDA's programs provide only limited protection against public exposure to prohibited pesticide residues on imported foods."

12(a) Does FDA believe this statement to be true today?

We believe FDA's programs provide adequate protection against public exposure to potentially harmful pesticide residues on imported food. FDA's experience with numerous years of pesticide surveys of the U.S. food supply, and on imported foods in particular, indicates that public exposure to prohibited pesticide residues on imported foods is low.

12(c) Would the imposition of a user fee on shipments of imported produce reduce the resource limitations under which GAO said the FDA operates?

User fees on shipments of imported produce would reduce the resource limitations of the FDA only if those fees were additive and were directed to the FDA for its use. User fees directed to the U.S. Treasury would not have any impact on FDA resources.

13. How will voluntary "Good Agricultural Practice/Good Manufacturing Practice" standards for fruits and

vegetables aid FDA in preventing contaminated produce from being imported into the United States? Without mandatory standards, how can FDA be certain that foreign growers are producing safe products?

FDA believes that the agricultural industry here and abroad will adopt the guidance if it is science-based and practical. Voluntary GAPs/GMPs guidance will be communicated to domestic and foreign growers through technical assistance, education, and outreach activities. The guidance will be based upon the best available science and will comprise an instructional tool for the industry to adopt to help minimize microbial risks associated with fresh produce. Agricultural, trade, and professional organizations have undertaken similar efforts to develop guidance for their members. This fact shows that the industry recognizes the need to promote and adopt affirmative measures to foster safe food growing and handling practices. Successful food safety programs both domestically and internationally have been implemented using voluntary initiatives. Mandatory programs have always been a consideration if the voluntary programs prove unsuccessful.

Of course, the Agency will continue to enforce the Federal Food, Drug, and Cosmetic Act which requires that all foods, domestic and imported, not be adulterated.

14. **Currently, food importers must meet the same standards as domestic food processors. However, vague terms, like "equivalent standards" and "appropriate levels of protection" can be used to change and weaken this requirement. Will the Administration's legislation require foreign food processors to meet the same standards as our domestic producers must meet, or will foreign food processors be permitted to meet standards that are "equivalent" to ours?**

Specific U.S. standards, such as pesticide tolerances, apply to all food marketed within the US whether the food is of domestic or foreign origin. The notion of "equivalence" as it is found in the Administration's legislation is in full accordance with that found in the Sanitary and Phytosanitary (SPS) Agreement (Agreement on the Application of Sanitary and Phytosanitary Measures, World Trade Organization). The principle of equivalence requires a country exporting food products to the U.S. to demonstrate to our satisfaction that the U.S.' level of public health protection will be met by the foreign country's food safety system.

15. How many laboratory tests is FDA currently doing to detect pathogens in imported fruits and vegetables? What have been the results of these tests?

In FY 97, approximately 2,510 laboratory tests were performed for pathogens. These tests were performed on 251 samples, the majority of which were collected for Cyclospora. FDA estimates that, for the 251 samples analyzed in FY 97, approximately 10 individual tests per sample were performed. FDA, depending on the reason for sampling, may test for aerobic plate counts, coliforms (including fecal coliforms) E. coli and for a specific pathogen or parasite if suspected.

Currently, FDA has no general assignments for monitoring imported fresh fruits and vegetables for the presence of pathogenic microorganisms. FDA has not routinely directed its field offices to collect and analyze samples of fresh produce for the presence of microbial, viral, or parasitic organisms because, in the past, these have not been recognized as a problem area. When information becomes available suggesting that some particular fresh produce may be contaminated, FDA directs field assignments as appropriate. FDA issues import alerts targeted to firms or products when problems have been identified. Assignments may include limited sampling of products as follow-up to reports of potential contamination.

Examples of these assignments include the coverage of imported fresh melons for Salmonella contamination in FY 91, Mexican produce for Vibrio cholerae in FY 91, imported fresh produce for Vibrio cholerae in FY 92, Mexican green onions for Shigella in FY 95, and, more recently, in FY 96 and FY 97, Guatemalan raspberries and Peruvian lettuce for Cyclospora.

As a result of these analyses, two products were found to contain evidence of a microbial, viral, or parasitic contamination. Samples of Mexican green onions collected for identification of possible contamination with Shigella were found not to contain this pathogen but did contain a high level of fecal coliforms which, while not pathogens, are an indication of unsanitary conditions. The product was detained. FDA sampling also identified imported fresh melons from Mexico for Salmonella in FY 90/91. In 1991, FDA provided recommendations to food retailers to reduce the risk of Salmonella in melons, and, in 1992, the produce industry implemented a voluntary Melon Quality Program. No melon-associated outbreaks have been reported since the implementation of this program.

Because of the sporadic nature of microbial, viral, or parasitic contamination and the difficulty in their detection, it is important to focus on prevention and intervention

strategies such as those being developed as part of the President's FSI. Guidance, in the form of (GAPs) and (GMPs), and research focused on preventing contamination during production are believed to be much more efficient and effective methods of preventing foodborne microbial contamination than end product testing.